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Summary of Safety and Effectiveness

DEC 2 2005

Contact Person: Karen Ariemma
Senior Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430
(201) 831-5718
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Date: November 29, 2005

Device: System 12® X3™ Acetabular Inserts
Series II™ X3™ Acetabular Inserts

Classification: Prosthesis Hip, Semi-Constrained, Porous Coated, Uncemented prosthesis: 21 CFR §888.3358

Hip Joint Metal/Ceramic/Polymer Semi-constrained cemented or nonporous uncemented prosthesis: 21 CFR §888.3353

Hip Joint Metal/Polymer Semi-Constrained Cemented Prosthesis, 21 CFR §888.3350

Device Product Codes: 87 JDI, 87 LPH, 87 LZO, and 87 MEH

Predicate Devices: System 12® and Series II™ Hip System Acetabular Inserts

Intended Use: The Stryker Orthopaedics System 12® X3™ Acetabular insert and Series II™ X3™ Acetabular insert components are single use sterile components intended for the replacement of

the bearing and/or articulating surfaces of the acetabulum to relieve pain, and the restriction of motion.

Indications for Use: The System 12® X3™ Acetabular Inserts are single use sterile components, intended for use in conjunction with associated acetabular shells, femoral bearings, and femoral hip stems as part of a cemented or cementless total hip replacement procedure. Indications for use are as follows: noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis; rheumatoid arthritis; correction of functional deformity; revision procedures where other treatments or devices have failed, and treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

The Series II™ X3™ Acetabular Inserts are single use sterile components, intended for use in conjunction with an associated Howmedica Osteonics metal acetabular shell, femoral bearing, and femoral hip stem as part of a cemented or cementless total hip arthroplasty. Indications for use are as follows: painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis, or late stage avascular necrosis; revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure; clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results; and where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Proposed Modification: Addition of new polyethylene components of a modified sequentially crosslinked and annealed material which has undergone a STERRAD gas plasma sterilization.

Device Description: The device includes the acetabular inserts of a total hip system. These components are used for the replacement of the bearing surface of the acetabulum to relieve pain, instability and the restriction of motion due to degenerative bone disease, including osteoarthritis, rheumatoid arthritis, failure of other devices or trauma.

Summary of Data: A risk analysis and research and development testing have been performed to demonstrate equivalence of the subject products to the predicate devices. Testing and analysis include material properties characterization, wear testing, disassembly force evaluation, and finite element modeling of contact stresses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 2005

Karen Ariemma
Senior Regulatory Affairs Specialist
Howmedica Osteonics Corporation
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K052748
Trade/Device Name: System 12® X3™ Acetabular Inserts, Series II™ X3™ Acetabular Inserts
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: JDI, LPH, LZO, MEH
Dated: September 29, 2005
Received: September 30, 2005

Dear Ms. Ariemma:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices is classified (see above) into either class II (Special Controls) or class III (PMA), they may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your devices as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your device and thus, permits your devices to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K052748 (pg 1 of 2)

Device Name: System 12® X3™ Acetabular Inserts

Indications for Use: The System 12® X3™ Acetabular Inserts are single use sterile components, intended for use in conjunction with associated acetabular shells, femoral bearings, and femoral hip stems as part of a cemented or cementless total hip replacement procedure. Indications for use are as follows:

- noninflammatory degenerative joint disease including osteoatrthritis and avascular necrosis,
- rheumatoid arthritis,
- correction of functional deformity,
- revision procedures where other treatments or devices have failed, and
- treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Prescription Use ____X____ OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052748

510(k) Number (if known): K052748 (pg 2 of 2)

Device Name: Series II™ X3™ Acetabular Inserts

Indications for Use:

The Series II™ X3™ Acetabular Inserts are single use sterile components, intended for use in conjunction with an associated Howmedica Osteonics metal acetabular shell, femoral bearing, and femoral hip stem as part of a cemented or cementless total hip arthroplasty. Indications for use are as follows:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis, or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Prescription Use ___X___ OR Over-the-Counter Use____ _____

(Per 21 CFR 801.109)

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